Synopsis: As the Board of Health considers secure medicine return, it must define the role of local government as well as that of the pharmaceutical producers and stewardship plan operators. In a product stewardship system, those who make and sell the covered products are responsible for operating and financing the take-back program for any of their unused products. Government oversight is necessary to ensure that the system meets requirements of the BOH regulation, including review and approval of plans as well as enforcement to ensure compliance as needed. Government also continues to play a public education role to help promote the take-back program.

Role of Local Government in a Product Stewardship System

Three roles are necessary for government: oversight, enforcement, and public education. For purposes of this staff report, "the Department" refers to the local government agency or agencies that assume these responsibilities.

Oversight. Review submitted stewardship plans for compliance with the regulation's requirements. Solicit and consider public comments as part of plan review. Approve or reject plan(s) as appropriate. Review plan updates as required under the regulation. Determine through various means if any pharmaceutical producers covered by the regulation are non-compliant. Review annual reports from approved take-back programs and approve any minor changes in plan(s) as operations dictate. Monitor implementation of stewardship plan(s) and inspect some collection sites or transfer facilities if needed to ensure that protocols in the approved plan(s) are being followed. Collect fees to cover governmental costs.

<u>Enforcement</u>. Receive complaints or referrals from oversight function. For non-compliant drug producers or any other non-compliant entities subject to the regulation, send warning letters and assess monetary penalties per provisions in the regulation. Amend, suspend or cancel approval of stewardship plan if noncompliance is not remedied, or if necessary to protect public health.

<u>Public education</u>. Assist the stewardship organization in promotion of the medicine take-back system. Continue involvement in the "Take Back Your Meds" educational programs to promote safe storage of medicines and use of the safe medicine return system. Target outreach campaigns to specific professionals such as medical and hospice practitioners, child care centers, PTA, school nurses, senior centers and realtors. Partner with collectors, including offering coupons or other incentives, to promote use of the system. Costs for these outreach functions will be covered by the Local Hazardous Waste Management Program in King County (LHWMP) as a shared responsibility for the program on an ongoing basis.

Fees for services provided by government will be based on the cost to provide said services – plan review, oversight activities, enforcement actions if plan non-compliant – similar to other environmental health program services and fees.

Considerations for this decision include:

- Minimal but essential government role overseeing a product stewardship program, including oversight and enforcement.
- Cost recovery via stewardship fees for this role.
- Shared-responsibility role for LHWMP funds for education activities.

Policy decisions to be made:

Approve or modify this direction for local government agencies to oversee and enforce the regulation.

Attachments:

- Policy Comparison Table: #6E "Oversight & Enforcement (Government Responsibilities)"